United States Court of Appeals

for the Second Circuit

BRIEF FOR APPELLEE

76-1353

To be argued by
LAWRENCE B. PEDOWITZ

United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 76-1353

UNITED STATES OF AMERICA,

Appellee,

—v.—

MARCEN LABORATORIES, INC. and
RAPHAEL A. MAROTTA,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIEF FOR THE UNITED STATES OF AMERICA

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United States Court of Appeals

FOR THE SECOND CIRCUIT

Docket No. 76-1353

UNITED STATES OF AMERICA,

Appellee,

—v.—

MARCEN LABORATORIES, INC. and
RAPHAEL A. MAROTTA,

Defendants-Appellants.

BRIEF FOR THE UNITED STATES OF AMERICA

Preliminary Statement

Marcen Laboratories, Inc. and Raphael A. Marotta, president of Marcen Laboratories, appeal from their judgments of conviction entered on July 27, 1976, after pleas of guilty, and from an order entered June 11, 1976, denying their motion to dismiss an Information charging them with violations of the new drug provisions of the Federal Food, Drug, and Cosmetic Act. Both proceedings were held in the United States District Court for the Southern District of New York before the Honorable Lloyd F. MacMahon, United States District Judge.

On December 15, 1975, Information 75 Cr. 1200 was filed, alleging that the defendants violated Title 21, United States Code, Section 331(d) on thirty-five separate occasions by causing the introduction and delivery into

interstate commerce of various "new drugs" within the meaning of Title 21, United States Code, Section 321(p), without an approved new drug application for any of the drugs as required by Title 21, United States Code, Section 355(b).

On January 20, 1976, Marcen Laboratories pled guilty to Counts 21, 22, 24 and 30 of the Information, and Raphael A. Marotta pled guilty to Count 31. Before accepting the pleas, the District Court approved a stipulation permitting the defendants to withdraw their pleas of guilty should there be a ruling in the District Court or on appeal that the statute on which the charges were based was unconstitutional.*

Thereafter, on January 30, 1976, the defendants moved to dismiss the Information principally on the ground that the definition of "new drug" found in Title 21, United States Code, Section 321(p), was unconstitutionally vague. On June 11, 1976, the District Court denied defendants' motion. *United States* v. *Marcen Laboratories, Inc.*, 416 F. Supp. 453 (S.D.N.Y. 1976) (App. 8a-12a).**

On July 27, 1976, Judge MacMahon sentenced Marcen Laboratories to a $1,000 fine on each of the four counts to which it had pled guilty. Raphael A. Marotta was sentenced on Count 31 to 10 days imprisonment and a $1,000 fine.

The defendant Marotta is at liberty pending this appeal.

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* This Court has approved appeals from the denial of suppression motions after pleas of guilty where similar stipulations have been entered into. See *United States* v. *Burke*, 517 F.2d 377, 378-79 (2d Cir. 1975); *United States* v. *Faruolo*, 506 F.2d 490, 491 n. 2 (2d Cir. 1974).

** The abbreviation "App." refers to appellants' appendix; and "Br." to their brief on appeal.

Statement of Facts

The defendants' principal claim below and on appeal is that the definition of "new drugs" contained in Title 21, United States Code, Section 321(p), is unconstitutionally vague in that it does not permit drug manufacturers to guide their conduct so as to avoid criminal liability. An understanding of the statutory scheme of the Federal Food, Drug, and Cosmetic Act and of the facts which led up to the filing of the Information in the instant case is necessary to a resolution of the issues presented.

A. Statutory Scheme

Title 21, United States Code, Section 321(p) provides that a drug is a "new drug" if it

> ". . . is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . ."

No person may introduce a "new drug" into interstate commerce (Title 21, United States Code, Section 355(a)), without first submitting substantial evidence of the safety and effectiveness of the drug to the United States Food and Drug Administration (FDA) in the form of a new drug application and obtaining prior approval for marketing. Title 21, United States Code, Section 355(b). Marketing a new drug without such approval is expressly prohibited. Title 21, United States Code, Section 331(d).*

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* Defendants incorrectly assert that the statutes involved in this appeal include Title 21, United States Code, Section 344. (Br. at 4-6). This reference is inexplicable since that section of

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Legislation prohibiting the interstate shipment of "new drugs" without FDA approval was first adopted in 1938. 52 Stat. 1052. Congressional recognition of the necessity for control of new drugs by preclearance procedures was the direct result of a medical tragedy in 1937 involving the deaths of nearly 100 persons who had taken the drug Elixir Sulfanilamide which had been marketed without prior tests and studies to assure its safety. *United States* v. *An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 797-98 (1969). The Drug Amendments of 1962 enlarged the definition of a new drug to include any drug not generally recognized by qualified experts as both safe *and effective* for its intended uses. 76 Stat. 781. Thus, the present new drug provisions evidence Congress' intent to protect the public by providing that unless qualified experts generally recognize a drug as safe and effective for its labeled uses, it may not be shipped in interstate commerce until the required evidence has been submitted to the FDA and the drug has been approved.*

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the Federal Food, Drug, and Cosmetic Act concerns only food contamination. Moreover, defendants mistakenly argue that the unconstitutionality of the new drug provisions is demonstrated "in Sections 344 and 345, whose complications and vagueness created the necessity for Section 321." (Br. at 10). This obvious error continues when defendants argue that the statute is vague insofar as "the sections cumulatively attempt to create a criminal offense." (Br. at 10).

* Judge MacMahon recognized the importance of this statutory scheme:

> "Drugs are products which require close supervision in the interest of the national health and welfare. To insure that, Congress has created the Pure Food and Drug Laws, and has put them under the administration of Food and Drug Administration, and if those laws are to be successful in their goal of protecting the public health and safeguarding people from dangerous drugs, they must be complied with." (App. at 48a-49a).

See also *AMP Inc.* v. *Gardner*, 389 F.2d 825, 830 (2d Cir.), *cert. denied sub nom. AMP Inc.* v. *Cohen*, 393 U.S. 825 (1968).

B. The Defendants' Unlawful Acts

The history of the defendants' dealings with the Food and Drug Administration put them on notice that it was the Government's position that they were illegally shipping new drugs in interstate commerce. As the defendants admitted at the time of their guilty pleas, and concede on appeal (Br. at 3), they were warned repeatedly, by court action and by direct communication with Government officials, that they were unlawfully shipping "new drugs." Nevertheless, they continued to ship these drugs in commerce without submitting proof of the effectiveness of the drugs.

With respect to the unlawful shipment of the drug Ossonate Plus injectable charged in Count 21, there had been two prior federal seizures of this drug from the defendants, because the drug was deemed by FDA to be a "new drug." There were also two prior hearings afforded these defendants pursuant to Title 21, United States Code, Section 335—hearings granted by FDA to parties as to whom criminal prosecution is contemplated. At both hearings Ossonate Plus injectable was charged to be a "new drug." As to the unlawful shipment of Normotensin charged in Count 22, there were two prior seizures of the drug from the defendants and one section 335 hearing identifying this drug as a "new drug." With respect to the shipment of Viro-Zyme injectable charged in Count 24, there had been a prior seizure from the defendants and two section 335 hearings identifying the drug as a "new drug." As to Count 30, involving a shipment of Lipo-K injectable, there were three prior seizures and one section 335 hearing identifying the drug as a new drug. (App. 41a-43a).

Finally, with respect to the shipment of Lipo-K capsules charged in Count 31—as to which the defendant Marotta pled guilty as an individual—there had been a prior section 335 hearing identifying this drug as a new drug. In addition, in 1971, the FDA announced in the

Federal Register that drugs such as Lipo-K capsules that contained methionine and choline had been found, after full administrative hearings, to be "new drugs."* Moreover, in 1972, a letter was sent to the defendant Marotta (App. 19a-20a), which he has acknowledged receiving, advising him personally as well as Marcen Laboratories of the action taken by FDA with respect to Lipo-K capsules. (App. 43a-44a).**

Furthermore, it was conceded that no adequate and well-controlled scientific studies—as those terms are defined by statute and federal regulation—had been conducted to evaluate the effectiveness of the drugs which the defendants caused to be shipped in interstate commerce. (App. 34a, 35a, 38a, 40a).

C. The District Court's Findings

After summarizing the above-mentioned facts which plainly demonstrated that the defendants had actual notice that the FDA considered the subject drugs "new drugs," the District Court rejected defendants' attack on the constitutionality of the statute. The Court noted the well-settled principle that, outside the First Amendment area, vagueness challenges must be evaluated in terms of the facts of each case. Since here the defendants were aware, before they shipped the subject drugs, that the

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* See 35 Fed. Reg. 396-97 (Jan. 10, 1970); 36 Fed. Reg. 5542 (Mar. 24, 1971); 36 Fed. Reg. 5639 (Mar. 25, 1971).

** The Supreme Court has held that declaration by the FDA that a drug is a new drug, after notice and correct procedures such as those followed with respect to Lipo-K capsules, is determinative of new drug status. *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973). The defendants had, but did not exercise, a right to judicial review of the agency's decisions which affected Lipo-K capsules. 412 U.S. at 653.

drugs were considered new drugs by the FDA for which no new drug application had been approved, they could not fairly claim an inability to guide their conduct so as to avoid criminal liability. (App. 8a-12a).

ARGUMENT

POINT I

Section 321(p) is neither vague on its face nor as applied to the facts of this case

The appellants contend that the definition of "new drug" contained in Title 21, United States Code, Section 321(p), is unconstitutionally vague on its face and as applied to the facts of this case. This claim is entirely without merit for three reasons: (1) section 321(p) is not facially vague; (2) well before the subject drugs were shipped in commerce, the Supreme Court authoritatively construed the term "new drug" in a manner which could have left the defendants no doubt that they were unlawfully dealing in new drugs; and (3) the history of defendants' dealings with FDA put them on notice that they were illegally shipping "new drugs."

A. Section 321(p) is facially valid

The definition of new drug in 21 U.S.C. § 321(p) is sufficiently definite to give a person of ordinary intelligence a reasonable opportunity to know what is prohibited by the statute. *Cf. Grayned* v. *City of Rockford*, 408 U.S. 104, 108 (1972). The definition contained in Section 321(p) has been upheld as sufficiently definite in a criminal context in *United States* v. *The Dow Corning Corp.*, Cr. No. 5381 (E.D. Mich., June 14, 1968), reported in Kleinfeld and Kaplan, *Federal Food, Drug, and Cosmetic*

Act: Judicial and Administrative Record 1965-1968 at 171.*

These decisions are consistent with numerous criminal cases upholding provisions of the Federal Food, Drug and Cosmetic Act against vagueness challenges. See, *e.g.*, *United States* v. *Wiesenfeld Warehouse Co.*, 376 U.S. 86, 89-91 (1964) ("doing of any act" which "results in such article being adulterated"); *United States* v. *Sullivan*, 332 U.S. 689, 695 (1948) and *United States* v. *Hohensee*, 243 F.2d 367, 370 (3d Cir.), *cert. denied*, 353 U.S. 976 (1957) ("adequate directions for use"); *United States* v. *Thriftimart, Inc.*, 429 F.2d 1006, 1011 (9th Cir.), *cert. denied*, 400 U.S. 926 (1970); *Golden Grain Macaroni Co.* v. *United States*, 209 F.2d 166, 168 (9th Cir. 1953); *Berger* v. *United States*, 200 F.2d 818, 822 (8th Cir. 1952) (each upholding the language "under insanitary conditions whereby it may have become contaminated with filth"); *United States* v. *Bel-Mar Labs, Inc.*, 284 F. Supp. 875 (E.D.N.Y. 1968) ("current manufacturing practices").

There is a very strong presumption in favor of the constitutionality of statutes. *United States* v. *National Dairy Products*, 372 U.S. 29, 32 (1963). When a statute is assailed as unconstitutional, the courts "have consistently sought an interpretation which supports the constitutionality of legislation."** *Id.* Moreover, "[i]n the field of

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* See also *United States* v. *2600 States Drugs, Inc.*, 235 F.2d 913, 915 (7th Cir.), *cert. denied*, 352 U.S. 848 (1956), in which a statutory scheme made up of, *inter alia*, 21 U.S.C. §355(a) and (b), which requires FDA approval of applications for new drugs, was held not to be unconstitutionally vague.

** This Court has upheld the constitutionality of statutory provisions in which arguably indefinite standards were attacked. See, *e.g.*, *United States* v. *Parness*, 503 F.2d 430, 440-42 (2d Cir. 1974), *cert. denied*, 419 U.S. 1105 (1975) ("pattern of racketeering activity"); *United States* v. *Deutsch*, 451 F.2d 98, 113-14 (2d

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regulatory statutes governing business activities, where the acts limited are in a narrow category, greater leeway is allowed" in upholding the statute. *Papachristou* v. *City of Jacksonville*, 405 U.S. 156, 162 (1972). This is particularly appropriate, as here, where a statute is addressed to a group of persons who are uniquely able to evaluate words and phrases which have a technical meaning.* See

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Cir. 1971), *cert. denied*, 404 U.S. 1019 (1972) ("acting as agent"). Some examples of language held to be constitutionally valid by the Supreme Court are *Cameron* v. *Johnson*, 390 U.S. 611, 616 (1968) "unreasonably interfere"); *Joseph E. Seagram & Sons* v. *Hostetter*, 384 U.S. 35, 48-49 (1966) ("substantial"); *United States* v. *Petrillo*, 332 U.S. 1, 6-8 (1947) ("in excess of the number of employees needed by such license to perform actual services"); *Gorin* v. *United States*, 312 U.S. 19, 27-30 (1941) ("connected with the national defense"); *Minnesota* v. *Probate Court*, 309 U.S. 270, 274-75 (1940) ("psychopathic personality"); *Kay* v. *United States*, 303 U.S. 1, 7 (1938) ("willfully overvalues any security"); *Bandini Petroleum Co.* v. *Superior Court*, 284 U.S. 8, 18 (1931) ("unreasonable waste of natural gas"); *Omaechevarria* v. *Idaho*, 246 U.S. 343, 348 (1918) ("range usually occupied by any cattle grower").

* For over 30 years Marcen Laboratories has made products which touch and affect the lives and health of the citizenry who, "in the circumstances of modern industrialism, are largely beyond self-protection." *United States* v. *Dotterweich*, 320 U.S. 277, 280 (1943). Neither the fact that drug chemistry and pharmacology are exacting sciences nor the fact that the defendant Marotta continued to argue that his drugs could be lawfully marketed without FDA approval excuse the defendants' violations of the law. The defendants can be presumed to know, and have a duty to know the food and drug law. *Cf. United States* v. *Park*, 421 U.S. 658 (1975). Any suggestion of ignorance, such as defendants' assertion that "general recognition" is not a term "which an individual in the drug industry can readily define" (Br. at 11), is wholly without foundation.

It is, moreover, in this context that the defendants' assertion that the United States has "conceded that the statute is vague on its face" should be evaluated. (Br. at 10). This allegation is apparently based upon comments made in oral argument at the

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Connally v. *General Construction Co.*, 269 U.S. 385, 391 (1926); *Hygrade Provision Co.* v. *Sherman*, 266 U.S. 497 (1925).* Nowhere is such judicial deference more appropriate than where the regulated activity directly affects the public health.

The Supreme Court has held that the Federal Food, Drug, and Cosmetic Act is to be interpreted with particular liberality, even in criminal cases:

> "The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation . . ." *United States* v. *Dotterweich*, 320 U.S. 277, 280 (1943).

See also *United States* v. *Park*, 421 U.S. 658, 668 (1975); *United States* v. *An Article of Drug . . . Bacto-Unidisk*, *supra*, 394 U.S. at 798.

January 20th proceeding, where the statute was referred to as one "which appears to be facially vague" or one with "fringes [that] may be vague". It is clear, however, that although this statute might appear unfamiliar to lay persons, it is well known to drug manufacturers and certainly to the defendants in the instant case.

* In *Hygrade*, the plaintiff sought to enjoin proceedings under a New York law prohibiting the sale of meat labeled "Kosher" if not sanctioned by orthodox Hebrew requirements. He contended that standards of "Kosher" were impossible to determine and the statute was therefore void for uncertainty. The Court stated:

> ". . . the evidence, while conflicting, warrants the conclusion that the term 'kosher' has a meaning well enough defined to enable one engaged in the trade to correctly apply it, at least as a general thing. If exceptional cases may sometimes arise where opinions might differ, that is no more than is likely to occur, and does occur, in respect of many criminal statutes either upheld against attack or never assailed as indefinite." 266 U.S. at 502.

B. Section 321(p) has been authoritatively construed to create a "core area" of violation into which defendants' conduct clearly falls.

But even assuming *arguendo* that the "generally recognized" definition of new drugs contained in 21 U.S.C. § 321(p), standing alone, might be considered vague, it is clear that this is one of those statutes which "by their terms or as authoritatively construed apply without question to certain activities," *Parker* v. *Levy*, 417 U.S. 733, 755-56 (1974); *Smith* v. *Goguen*, 415 U.S. 566, 578 (1974), and the conduct of the defendants quite plainly falls within the core area of this statute.

In *Weinberger* v. *Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609, 629-32 (1973), the Supreme Court construed the requirement of "general recognition" in Section 321(p), holding that it must be based upon "substantial evidence", which is defined in detail by the statute. The Court found no difficulty with the statutory language, and the Court's opinion contains no suggestion of vagueness whatsoever. In explaining its ruling, the Court stated:

> "[T]he statutory scheme and overriding purpose of the 1962 amendments compel the conclusion that the hurdle of 'general recognition' of effectiveness requires at least 'substantial evidence' of effectiveness for approval of [a new drug application]. In the absence of any evidence of adequate and well-controlled investigation supporting the efficacy of [a drug]; *a fortiori* [that drug] would be a 'new drug' subject to the provisions of the Act." *Id.* at 629-30.

The Court then made clear that by "substantial evidence", it was referring to the definition of that term contained in Title 21, United States Code, Section 355(d):

> "We accordingly have concluded that a drug can be 'generally recognized' by experts as effective for intended use within the meaning of the Act only when that expert consensus is founded upon 'substantial evidence' as defined in [Title 21, United States Code, Section 355(d))." *Id.* at 632.*

Section 355(d) defines "substantial evidence" as:

> "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

Adequate and well-controlled investigations which are required for substantial evidence to exist must meet the objective criteria set forth in detailed federal regulations, see 21 C.F.R. § 314, 111(a)(5)(ii) (Part 130 at the time of the Supreme Court's opinion).

It is thus clear that a drug for which there is no substantial evidence of effectiveness, as defined in detail by the Act and regulation, is a "new drug," and causing the

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* As the Supreme Court stated in *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973), a companion case, "the reach of scientific inquiry under both [Section 355(d) and 321(p)] is precisely the same."

interstate shipment of such a drug, absent FDA approval, is, without question, a crime. Therefore, shipment of a drug for which no adequate and well-controlled investigations exist is an offense within the "core" of the statute. *Cf. Broadrick* v. *Oklahoma*, 413 U.S. 601, 608 (1973); *Dombrowski* v. *Pfister*, 380 U.S. 479, 491-92 (1965). Since the defendants admitted at the time of their plea that there existed for the drugs they shipped no adequate well-controlled studies within the meaning of both Title 21, United States Code, Section 355(d) and the pertinent federal regulations (App. at 34a, 35a, 38a, 40a), defendants' conduct fell squarely within the "hard core" of the new drug provisions.

The defendants response to all of this is simply that the Supreme Court in *Hynson* "upheld the definition of 'new drug' for the purposes of civil enforcement," and that an interpretation of a statute in a civil context "cannot serve to clarify a vague criminal statute." (Br. at 12). It is not surprising that this legal assertion is unaccompanied by any citation of authority, since it is well-settled that precedents in civil cases may be used to establish statutory standards which must be complied with in criminal cases. See *United States* v. *Persky*, 520 F.2d 283, 288 (2d Cir. 1975); *United States* v. *Clark*, 359 F. Supp. 128, 130 (S.D.N.Y. 1973); see also *International Harvester Co.* v. *Kentucky*, 234 U.S. 216, 223 (1914); *United States* v. *Peltz*, 433 F.2d 48, 53 (2d Cir. 1970), *cert. denied*, 401 U.S. 955 (1971).*

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* In *Weinberger* v. *Bentex Pharmaceutical, Inc.*, *supra*, 412 U.S. 645, a companion case to *Hynson*, the Supreme Court held that the FDA had the power to decide with administrative finality, subject to judicial review, the "new drug" status of individual drugs. Defendants argue that the *Bentex* decision would permit the Government to prove the guilt of a defendant by showing nothing more than that the defendant introduced a drug into interstate commerce which the FDA had previously declared with

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C. Section 321(p) is, in any event, not vague as applied to the facts of this case

In any event, since the defendants were repeatedly warned by the FDA that they were dealing unlawfully in "new drugs," it is plain they cannot successfully attack the statute as vague.

While the Supreme Court has carved out a narrow exception from its normal rules of standing which permits a defendant to attack as overbroad and vague a statute substantially impinging upon First Amendment freedoms even though the statute is not vague or overboard when applied to the defendant's own conduct, see *Dombrowski* v. *Pfister*, *supra*, 380 U.S. at 486-87,* it is well settled "that vagueness challenges to statutes which do not involve First Amendment freedoms must be examined in the light of the facts of the case at hand." *United States*

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administrative finality to be a "new drug." (Br. at 12-13). The Government does not disagree with this contention, though only in the case of Lipo-K capsules has there been such an administrative determination by the FDA. See p. 5-6, *supra*.

When the FDA—an agency with significant expertise—determines after notice and hearing, subject to judicial review, that a drug is a "new drug", there is no reason why that determination should not be conclusive for purposes of a criminal proceeding. Such a procedure is precisely analogous to that provided for in 21 U.S.C. § 811, which permits the Attorney General, after administrative rulemaking procedures, to add drugs that have a potential for abuse to the list of controlled substances which may not lawfully be distributed. But even if a determination of "new drug" status by the FDA were found inadequate to meet the requirements of criminal due process, the Government would be prepared, as it stated it would be in this case, to call expert witnesses to testify that there exist no adequate and well-controlled studies demonstrating the effectiveness of the subject drug. (See App. 63a-64a).

* See also *Gooding* v. *Wilson*, 405 U.S. 518, 520-21 (1972); *Coates* v. *City of Cincinnati*, 402 U.S. 611, 619-20 (1971) (White, J., dissenting).

v. *Mazurie*, 419 U.S. 544, 550 (1975); see *Parker* v. *Levy*, *supra*, 417 U.S. at 756; *Broadrick* v. *Oklahoma*, *supra*, 413 U.S. at 608. Since the defendants have made no claim that this case implicates First Amendment freedoms, and fairly could not make such a claim, the relevant issue becomes whether the defendants, in the factual context in which they found themselves, had a reasonable opportunity to "know what [was] prohibited" by the statute. *Grayned* v. *City of Rockford*, *supra*, 408 U.S. at 108. *Cf. United States* v. *Mazurie*, *supra*, 419 U.S. at 550; *United States* v. *National Dairy Products Co.*, *supra*, 372 U.S. at 36.

Defendants are scarcely in a position to argue that a person of reasonable intelligence in their position could not have had a reasonable opportunity to know they were shipping prohibited drugs. The District Court's opinion summarized the prior court actions, administrative hearings, and other direct communication from the FDA by which defendants were repeatedly warned that the drugs they shipped were "new drugs":

> "Defendants were aware, with respect to every count to which they pled guilty, that the drugs were considered to be 'new drugs' without an approved NDA (new drug application). . . . [Both defendants] received actual notice that the FDA considered the subject drugs 'new drugs' and knew that there was no effective NDA permitting their sale. . . ." (App. at 11a).*

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* Indeed, defendants themselves admit that they "clearly had notice that the Food and Drug Administration considered [their] drugs to be new drugs within the meaning of the statute" (Br. at 11), and concede that they were so notified "on numerous occasions". (Br. at 3).

While it is true that the defendants continued to disagree with the FDA about the application of the Act to their drugs (see Br. at 11), a defendant is not excused from a violation of law simply because he adheres to an interpretation of law that differs from that of the agency charged with enforcing it. The relevant question is not whether the defendants voiced their disagreement with FDA, but whether they had a reasonable opportunity to conform their conduct to that required by law. As the Supreme Court noted in *Boyce Motor Lines* v. *United States*, 342 U.S. 337, 340 (1952), in the area of business regulation, "[it is not] unfair to require that one who deliberately goes perilously close to an area of proscribed conduct shall take the risk that he may cross the line." *

POINT II

The new drug provisions do not violate the Confrontation Clause of the Sixth Amendment.

Defendants argue that Section 321(p) violates the Confrontation Clause of the Sixth Amendment. More specifically, they contend that the phrase "generally recognized, among experts qualified by scientific training and experience" is a subjective measure of reputation which can only be determined by the "collective opinion

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* Defendants note that sixteen of its drugs were seized under the Act and that in 1969 Marcen, after filing a claim and answer, withdrew without admitting the allegations (and also therefore without challenging the merits of those allegations.) (Br. at 3-4). Defendants point out that Marcen ceased marketing nine of the drugs and was to have submitted "drastically" revised labeling for seven others, including the drugs to which the defendants pled guilty to having shipped in this case. (App. at 79a). The Government is unable to determine why it is that the defendants believe it appropriate to refer to these facts, since the labeling revisions were never approved by the FDA and the 1969 seizure establishes the defendants' complete awareness of the illegality of their conduct.

of an undefined group," since the "true accuser" presents subjective hearsay and is not available for cross-examination. (Br. at 11, 13-14). This claim is meritless.

A claim that subjective, expert judgment could not provide a basis for criminal prosecution was rejected by the Supreme Court in *Doe* v. *Bolton*, 410 U.S. 179, 191-92 (1973), where the Court upheld against a vagueness challenge the statutory language "based upon his best clinical judgment that an abortion is necessary." There, as here, it was alleged that "the statute is wholly without objective standards and is subject to diverse interpretation."

But even more importantly, the standard—"general recognition" by experts—does not exist in a vacuum. General recognition must be based upon "substantial evidence", that is, adequate and well-controlled clinical studies. Title 21, United States Code, Section 355(d); *Weinberger* v. *Hyson, Westcott and Dunning, Inc., supra.* Defendants prefer to ignore the narrowed definition of new drugs and instead focus selectively only on the words "general recognition". This posture is contrary to the Supreme Court's admonition that the Act must not be treated "merely as a collection of English words" but rather as "a working instrument of government." *United States* v. *Dotterweich, supra*, 320 U.S. at 280.

Once it is recognized that the test of general recognition requires an analysis of whether there is substantial evidence demonstrating the safety and effectiveness of the subject drug, the proper question becomes whether there exist any adequate and well-controlled clinical studies demonstrating safety and effectiveness. This test is clearly objective. Moreover, no one is deprived of an opportunity to confront his accusers. The Government proves its case by presenting the testimony of eminent

physicians and other experts that, while familiar with the literature in their field, they are unaware of the existence of any adequate and well-controlled tests demonstrating the safety and effectiveness of the disputed drugs. Cross-examination will provide an opportunity to challenge the bases for the experts' testimony, and evidence can be introduced to demonstrate the possible existence of studies of which the expert is unaware. (See App. at 63a-64a, 68a).

At base, defendants appear to argue that Congress cannot constitutionally prohibit conduct that is measured by reference to expert testimony and/or opinion. No authority is cited for this novel proposition, and the absence of such authority is dramatic proof of its insubstantiality.*

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* There can be no question that opinion testimony is admissible to establish an ultimate fact. *United States* v. *Fernandez*, 480 F.2d 726, 740 (2d Cir. 1973); *Schroeder* v. *C. F. Braun & Co.*, 502 F.2d 235, 243 (7th Cir. 1974). See Fed. R. Evid. 704. Indeed, expert witnesses in criminal trials are commonplace. See *Ivy* v. *Katzenbach*, 351 F.2d 32, 34 (7th Cir.), *cert. denied*, 382 U.S. 958 (1965) (a case brought to enjoin criminal prosecution under the Federal Food, Drug, and Cosmetic Act). The use of expert testimony of 'general recognition" has been specifically upheld in establishing new drug status. *United States* v. *An Article of Drug . . . Furestrol Vaginal Suppositories*, 415 F.2d 390, 392, 393 (5th Cir. 1969). There is no requirement that the medical community at large be surveyed. *United States* v. *Wood*, 226 F.2d 924 (4th Cir. 1955).

POINT III

The District Court's sentence was not excessive.

The District Court imposed a fine of $1,000 upon defendant Marotta and sentenced him to 10 days imprisonment. Marotta argues that the penalty is excessive. (Br. at 15). This claim is ill-founded.

Marotta ignores the settled law in this Circuit that:

> ". . . absent reliance on improper considerations, see *United States* v. *Mitchell*, 392 F.2d 214, 217 (2d Cir. 1968) (Kaufman, *J.*, concurring), or materially incorrect information, see *United States* v. *Malcolm*, 432 F.2d 809, 816 (2d Cir. 1970), a sentence within statutory limits is not reviewable. See, *e.g.*, *United States* v. *Brown*, [479 F.2d 1170, 1172 (2d Cir. 1973)]; . . . *United States* v. *Dzialak*, 441 F.2d 212, 218 (2d Cir.), *cert. denied*, 404 U.S. 883 (1971)." *United States* v. *Velazquez*, 482 F.2d 139, 142 (2d Cir. 1973).

Accord, *Dorszynski* v. *United States*, 418 U.S. 424, 440-441 (1974); *United States* v. *Tucker*, 404 U.S. 443 (1972); *Gore* v. *United States*, 357 U.S. 386, 393 (1958); *United States* v. *Hendrix*, 505 F.2d 1233 (2d Cir. 1974).

Marotta has not made, and could not fairly make, any claim that there was reliance by the Court on improper considerations or incorrect information. The fact is that Judge MacMahon relied on the record in the case itself, which showed that Marotta's violations were "persistent . . . even defiant." (App. 48a). While Marotta claims that this is his "first involvement with the law", the record reveals that he has been the subject of numerous civil seizure actions and administrative proceedings, and has received numerous written communications from the

FDA notifying him of his deviations from law. What Marotta chooses to call his "tenacity" (Br. at 15), Judge MacMahon properly found to be stubbornness of a most serious sort.*

The Act which Marotta violated authorizes up to one year's imprisonment. There is no reason for this Court to modify Judge MacMahon's ten-day sentence.

CONCLUSION

The judgments of conviction and the order denying the motion to dismiss should be affirmed.

Respectfully submitted,

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* Judge MacMahon's comments concerning the seriousness of the statutory offenses in this case were particularly apt. Lipo-K capsules, for example, for which there is no proof of effectiveness, were labeled by the defendants as useful in the treatment of heart disease, more specifically, angina pectoris, atherosclerosis and peripheral vascular diseases. The prospect that seriously ill persons may have relied on the labelling on these drugs without knowing that there is no proof of the drug's effectiveness is simply frightening.

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AFFIDAVIT OF MAILING

STATE OF NEW YORK)
COUNTY OF NEW YORK) ss.:

Lawrence B. Pedowitz, being duly sworn, deposes and says that he is employed in the office of the United States Attorney for the Southern District of New York.

That on the 29th day of October, 1976, he served a copy of the within brief by placing the same in a properly postpaid franked envelope addressed:

Joseph P. Altier, Esq.
Bromsen, Gammerman, Altier & Wayne
450 Seventh Ave.
New York, N.Y.

And deponent further says that he sealed the said envelope and placed the same in the mail box for mailing at One St. Andrew's Plaza, Borough of Manhattan, City of New York.

Lawrence B. Pedowitz

Sworn to before me this
29th day of October, 1976

Gloria Calabrese

GLORIA CALABRESE
Notary Public, State of New York
No. 24-0535340
Qualified in Kings County
Commission Expires March 30, 1977